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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/519,212 | 12/27/2004 | Katsuhisa Mitsuhashi | 04853.0121 | 7322 |
| 22852 | 7590 | 11/15/2005 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| | | LILLING, HERBERT J | | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1651 | | |

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/519,212 | MITSUHASHI ET AL. | |
| | Examiner | Art Unit | |
| | HERBERT J. LILLING | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 May 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

The prior office action mailed November 01, 2005 has been withdrawn due to missing information.

1. Receipt is acknowledged of the foreign priority papers filed May 17, 2005 and the prior art information disclosure statements filed December 27, 2004 and February 17, 2005.

2. Claims 1-23 are pending in this application which is a 371 of PCT/JP03/08217 filed June 27, 2003 which claims benefit to Japan 2002-1906 16 filed June 28, 2002.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12 and 14-21, drawn to a method of producing a lactone comprising culturing *Candida sorbophila*.

Group II, claim 23, drawn to a *Candida sorbophila* strain BP-8388.
It is noted that this claim is drawn to a product of nature.

Group III; claim 13 whereby the product is drawn to a recovered precursor.

Claim 22 is a non-statutory claim, which cannot be properly classified as to a product, composition or process claim.

The inventions are distinct, each from the other because:

Inventions II and I or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be employed in a materially different process of using that product.

Inventions III is drawn to a distinct product than that of Invention I. which requires

In addition, Invention I does not require the specifics of Invention II.

Invention I does not require the specifics of Invention III.

In addition, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different components obtained or used, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper which above distinctions would be extremely burdensome to search and examine all of the inventions as well as the species as noted in the following paragraph.

Further, in view of the following that the claimed subject matter has been considered not so linked to form a single general inventive concept under PCT Rule 13.1 as recited for documents:

Document 1: WO, 3/01072, A @RITZSCHE DODGE & OLCOW mC.), 31 March 1983.

Document 2: EP, 371568, A1 BVER NV), 06 June, 1990.

Document 3: JP, 61-195693, A Xanebo Ltd.), 29 August 1986.

Document 4: D, 60-66991, A (Kanebo Ltd.), 17 April, 1985.

Document 5: EP, 356291, A1 (PBRNOD-RICARD), 28 Feb, 1990.

The inventions described in claims 1-23 do not appear to involve an inventive step based on above documents 1-5 cited in the ISR whereby

Documents 1-4 describe a method for the manufacture of lactones by culturing microorganisms belonging to a *Candida* class in a culture using castor oil as a substrate and recovering the produced lactones. Furthermore, document 1 describes a method for the manufacture of optically active lactones. Moreover, as described in document 5, manufacturing optically active lactones by using 1.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Whereby the method is drawn to producing a lactone from the medium comprising culturing *Candida sorbophila* from a substrate consisting of:

- A1. Hydroxy fatty acid;
- A2. hydroxy fatty acid derivative;
- A3. hydrolysate of a fatty acid derivative.

Election of one of the above substrates for claims 1 or 2.

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B. Whereby the method is drawn to producing a lactone from the medium comprising culturing *Candida sorbophila* from a substrate consisting of hydroxy fatty acid, hydroxy fatty acid derivative or hydrolysate of a fatty acid derivative and recovering the lactone:

Bx. directly from the medium.

By. lactonizing a lactone precursor hydroxy fatty acid produced in the medium.

Claims 3, 4, 5, 11, 12, will be examined with the above elected species selected from A, [1,2 or 3] or from B [x or y].

Claim 6 will be examined with the election consistent with the election of the hydroxy fatty acid which is generic to claims 1 and 2.

C. Claim 7 will be examined with the election consistent with the election of the hydroxy fatty acid derivative, which is generic to claims 1 and 2 with the further election for the derivative selected from:

Ci. alkyl ester of hydroxy acid;

Cii. glyceride of hydroxy fatty acid.

Claims 8 or 9 will be examined with the above election (i) or (ii).

D. An election of the medium containing the following is required:

Da. Castor oil or castor oil hydrolysate;

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- Db. Ricinoleic acid;
- Dc. 10 or 11-hydroxypalmitic acid;
- Dd. Isquerolic acid;
- De. 10-hydroxysteraric acid ;
or
- Df. Ethyl 11-hydroxypalimate.

E. A method for producing a lactone precursor whereby the method is drawn to producing a lactone from the medium comprising culturing *Candida sorbophila* from a substrate consisting of hydroxy fatty acid; hydroxy fatty acid derivative or hydrolysate of a fatty acid derivative which is produced:

E1. in the medium without any recovery of the lactone precursor;

Or

E2. the lactone precursor is recovered.

Applicant is required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention [Inventions as noted above I, II or III] and election of the species [A 1 or A2 or A3] plus [Bx or By] plus [Ci or Cii] plus [Da or Db or Dc or Dd or De or Df] plus [E1 or E2] which is consistent with the elected invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. **F.P.: Ochiai/Brouwer Rejoinder form paragraph**

This examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims

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in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. The has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is (703) 872-9306** or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1651
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Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651